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EXAMINER	
POLANSKY, GREGG	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,471	EHRICH ET AL.	
	Examiner	Art Unit	
	GREGG POLANSKY	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8,10-16 and 18-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8,10-13 and 21-27* is/are rejected.

7)☐ Claim(s) *14-16 and 18-20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 January 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/04/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicants' response, filed 3/04/2010, to the Office Action mailed 12/04/2009 is acknowledged. Applicants canceled Claim 28 and presented arguments in response to the Office Action.

2. Applicants' Information Disclosure Statement, filed 3/04/2010, is acknowledged and has been reviewed to the extent of the English language Abstracts of the cited foreign language documents.

3. Applicants' arguments have been fully considered and are deemed to be persuasive in part. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

4. Claims 1, 2, 4-8, 10-16, and 18-27 are pending and presently under consideration.

Drawings

5. The drawings are objected to because the drawing labeled FIG. 3 has what appears to be a typographical error. The 2nd line of the legend recites "TrCl/DPSC/DPPC/Leucine (5/5/5/85)". "DPSC" should be "DSPC". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should

include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

6. Claims 14-16 and 18-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 2, 4, 5, and 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freund et al. (U.S. Patent Application Pub. No. 2001/0008632 A1; previously cited), in view of Richards et al. (U.S. Patent Application Pub. No. 2003/0158176; previously cited) and Levin et al. (The American Journal of Medicine, 1996, Vol. 100, Sup. 1, pp. S40-S48, Abstract only; previously cited).

Freund et al. teach aqueous aerosols of *inter alia* anticholinergic agents, including trospium chloride and ipratropium bromide (*see* page 2, paragraphs 20, 21 and 23), and betamimetics, including formoterol, salbutamol, and fenoterol (see page 2, paragraphs 36 and 37) for inhalation in the treatment of respiratory passage diseases (*see* page 1, paragraph 7 and page 3, claim 2). In instant case, the instantly claimed trospium is disclosed by Freund et al. in a short list of 4 anticholinergic agents. The instantly claimed formoterol is disclosed by Freund et al. in a short list of 4 betamimetics.

The reference teaches the active ingredients can be used singly or in combination. Freund et al. also teach an active agent concentration range of 10mg/100ml to 20000mg/100ml and a nebuliser delivering 12 microliters of concentrate per operation (*see* page 3, paragraph 52). Therefore, the dose of active agent would be between 1.2 mcg and 2400 mcg per operation.

The duration of action of the trospium formulations are dose dependent. For example, Richards et al. disclose increasing the dose of the anticholinergic agent disclosed by Example 2 "produce increasing durations of action." See Figures 1-3 and page 15, paragraph 238. Accordingly, the relationship of the dose of trospium to the duration of action is a characteristic of trospium. Since Freund et al. teach a dose range which encompasses the instantly claimed dose range, the duration of action of trospium taught by Freund et al. would be the same as that of the instant invention.

Levin et al. teach administration of an anticholinergic agent in combination with a β2 agonist in the treatment of COPD. The anticholinergic agent (ipratropium, 500 micrograms) and the β2 agonist (albuterol/salbutamol, 2.5 mg) are administered by inhalation using a small volume nebuliser, according to Levin et al. The combination produced a greater therapeutic effect than the agents administered separately. See Abstract. Ipratropium is one of the 4 anticholinergics disclosed by Freund et al. (which also includes the instantly claimed trospium). Albuterol (also called salbutamol) is one of the 4 betamimetics disclosed by Freund et al. (which also includes the instantly claimed formoterol).

Richards et al. teach anticholinergic (antimuscarinic) agents, including the compound, trospium, are useful for the treatment of acetylcholine-mediated disorders, in particular, the treatment of *inter alia* chronic obstructive pulmonary disease (COPD) and asthma (*see* page 5, paragraphs 91 and 93). Richards et al. teach the advantageous administration of anticholinergic agents by inhalation or insufflation in the form of an aerosol or a dry powder (administered by dry powder inhaler (*see* page 6, paragraphs 103 and 106). Richards et al. teach that dose of anticholinergic agents depends on many factors, including the potency of the compound, the age and weight of the patient and the severity of the condition (*see* page 6, paragraph 105). One of ordinary skill in the art would have optimized the doses taught by Freund et al. and Levin et al. to maximize the therapeutic effects, including duration of action, and minimize the deleterious effects of the active agent.

One of ordinary skill in the art (e.g., a pulmonologist) would have found it obvious to combine these three teachings to treat diseases such as COPD and asthma by local (i.e., inhalation) administration of trospium and an additional agent, such as formoterol. Levin et al. teach the usefulness of treating COPD with a combination of (by inhalation) an anticholinergic agent (ipratropium) and a β2 agonist (salbutamol). Freund et al. teach the usefulness of *inter alia*, anticholinergics and betamimetics (including trospium and formoterol, respectively) for treating respiratory passages diseases and Richards et al. teach COPD and asthma as two respiratory diseases effectively treated by trospium. One would have been motivated to administer the active agents via inhalation to directly target the respiratory system, thereby minimizing the amount of active agents

administered systemically, thus avoiding excessive systemic absorption and resulting undesirable systemic effects, and to improve upon the known methods of treatment for COPD and asthma (as disclosed by Richards et al.). One of ordinary skill in the art would have found it obvious to substitute one known element (e.g. trospium) for another (e.g. ipratropium).

10. Applicants argue they "are claiming a method of delivering a specific drug in a composition at a drug dosage range that provides a specific therapeutic effect. Freund does not disclose this [instant invention] "species". Freund discloses a list of drugs and a list of dosage ranges. In order to arrive at the presently claimed "species" based on Freund's disclosure, one must first pick from Freund's disclosure the specific drug, trospium, and then one must make a second choice regarding the specific dosage that result in 10 hours of therapy. Freund gives a generalized dosage range from 10 mg to 20,000 mg/100 ml for all 100 drugs. This dosage range is huge. Certainly one of skill in the art would not conclude from this range that all 100 drugs are effective across the entire range, or effective for 10 hours across the entire range, or that this range is equally applicable to each and every drug listed therein. Thus Freund has not disclosed the specific, presently claimed "species". Applicants further assert "the 10 hour duration of trospium is dose dependent. … However, Freund does not disclose, suggest or recognize any such relationship between any dose and the duration of any effective therapy. Applicants are the first to correlate at least 10 hours duration of therapy of trospium with a specific dosage range of trospium." Applicants opine "[t]he Examiner's analysis based on Freund relies on the person of skill in the art to know what the dose

of any drug should be to achieve a desired therapy, to then calculate the amount required to be present in 12 microliters and then determine the concentration of the drug in the formulation. The Examiner has yet to provide any substantive arguments how a skilled person can know these things without the benefit of the present disclosure."

Applicants allege neither Levin et al. nor Richards et al. rectify the deficiencies of Freund.

Applicants argue "Richards discloses the synthesis and testing of novel anti-muscarinics that are very different from trospium…[and] teaches nothing about dosage or formulation or hours of therapeutic effectiveness of trospium…. Given that the compounds in Richards are structurally different from trospium there is no basis for the Examiner's assumption that Richards provides any useful information with regard to the optimization of dosages and formulations of trospium which achieve effective therapy for at least 10 hours, either alone or in combination with Freund".

First, it is noted that independent Claim 1 of the present application is quite broad. The claim can be reasonably interpreted to allow for administration of multiple doses of trospium to achieve "an effective therapy for at least 10 hours" of a disease which is only characterized by the presence of a constrictive airway. One of ordinary skill would have certainly recognized that the duration of action of any therapeutic agent could be extended by multiple dosing of the agent.

With regard to Applicants' assertion that they "are the first to correlate at least 10 hours duration of therapy of trospium with a specific dosage range of trospium", it is noted that Applicants also have demonstrated a correlation between duration of action

and dose for ipratropium bromide. See, for example, instant Figure 1A. Richards et al. similarly teach that increasing the dose of the anticholinergic agent disclosed by Example 2 "produce increasing durations of action." See Figures 1-3 and page 15, paragraph 238. One of ordinary skill would have considered this disclosure by Richards et al. in optimizing the dosage of trospium to achieve a desired therapeutic duration.

With regard to instant Claims 22-26, Applicants argue the references cited in the rejection provide no motivation to "combine trospium with any other active agent, such as beta-2 agonists or formoterol, while maintaining the claimed duration of therapy of trospium." Applicants argue "[n]either Freund nor Richards disclose a species wherein trospium is delivered in combination with a beta-2 agonist. Levin discloses a different compound, ipratropium, delivered with a B2 agonist, albuterol. … Freund does not disclose a species wherein trospium is delivered in combination with formoterol. While both trospium and formoterol are listed in the same 100+ drug list in Freund, there is no motivation provided by Levin or Richards for concluding that this very specific combination would be chosen". Applicants argue Freund does not teach the limitation of instant Claim 25 wherein the 2nd active agent is administered separately from the trospium formulation.

This argument is not persuasive. As discussed above, Levin et al. teach administration of an anticholinergic agent in combination with a β2 agonist in the treatment of COPD. The anticholinergic agent, ipratropium, and the β2 agonist albuterol/salbutamol, are administered by inhalation. Ipratropium is one of the 4 anticholinergics disclosed by Freund et al. (which also includes the instantly claimed

trospium). Albuterol (also called salbutamol) is one of the 4 betamimetics disclosed by Freund et al. (which also includes the instantly claimed formoterol). One of ordinary skill in the art would have found it obvious to substitute one known element (e.g. trospium) for another (e.g. ipratropium). Freund teaches the equivalence of trospium and ipratropium as anticholinergic agents (among 4 disclosed anticholinergic agents) and the equivalence of formoterol and albuterol as β2 agonists (among 4 disclosed β2 agonists). As presented above, Freund teaches formulation active ingredients can be used singly or in combination. This also would have been obvious to one skilled in the art.

11. Claims 1, 2, 4-8, 10-13, and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freund et al. (*supra*), in view of Richards et al. (*supra*) and Levin et al. (*supra*), as applied to Claim 1, 2, 4, 5, and 22-27 above, and further in view of Bernstein et al. (U.S. Patent Application Pub. No. 2004/0105821 A1; previously cited).

Bernstein et al. teach particulate sustained release pharmaceutical formulations for inhalation administration. See Abstract. The sustained release dry powder formulations are disclosed to be useful in the treatment of respiratory disease, including *inter alia* asthma and COPD. Further, the sustained release formulation provides local or plasma concentrations at nearly constant values over the intended period of release (for example, up to 2 to 24 hours), allowing patients to take treatments once or twice daily. See page 13, paragraphs 184, 189 and 190. Bernstein et al. teach anticholinergic agents (such as ipratropium bromide) and bronchodilator/sympathimetic

agents (such as formoterol) may be formulated by the methods disclosed. See pages 8-9, paragraphs 92 and 123. Although Bernstein et al. do not teach trospium *per se*, they do teach anticholinergic agents in general. Freund et al. also teach anticholinergic agents can be administered by dry powder formulation, as well as specifically teaching both ipratropium bromide and trospium. One of ordinary skill in the art at the time of the invention would have understood (especially in light of the teaching of Freund et al.) that one known anticholinergic agent (i.e., trospium) could be substituted for another (i.e., ipratropium) with a reasonable expectation of success. The formulations disclosed by the reference utilize spray drying techniques. See page 10, paragraph 148, and page 11, paragraphs 159-162. The aerodynamic diameter of the formulation is adjusted to enable particle deposition by inhalation to the region of interest in the lung. See pages 4-5, paragraphs 44 and 52. Particles taught by Bernstein et al. have a volume average diameter and volume median diameter of between 1 and 5 microns, and a tap densities ranging from 0.22 to 0.68 g/mL, and at least 50% by weight of the microparticles delivered to the lung is delivered to the central and upper lung; these disclosures satisfy the requirements of instant Claims 8 and 10-12. See page 5, paragraph 57; page 14, Table 1; and page 15-16, claims 4, 5 and 21. The reference teaches the inclusion of surfactants (e.g., lipids), including phospholipids and bulking agents (e.g., amino acids), including leucine, in the formulations. See page 2, paragraph 14; page 6, paragraph 68; page 10, paragraphs 143 and 144; and pages 15-16, claims 10 and 31. The surfactants comprise less than 10% by weight of the microparticles and 0.1 to 5% of the

formulation. See page 7, paragraph 79 and page 12, paragraph 171. The active pharmaceutical agent is present from about 5 to 50 wt %. See page 9, paragraph 138.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the above 4 references to create an effective treatment for respiratory diseases, such as COPD, that was administered by inhalation to target the lungs and reduce undesirable systemic effects, and long lasting so as to allow for once daily administration. The reference to Levin et al. teaches the therapeutic benefit of administration by inhalation of the combination of ipratropium (an anticholinergic agent) and salbutamol (a β2 agonist) in the treatment of COPD. Freund et al. and Richards et al. teach suitable therapeutic agents and routes of administration for treating COPD and asthma, and Bernstein et al. teach methods for creating sustained release formulations of active agents suitable for treating respiratory conditions, including COPD. One would have been motivated combine the teachings to improve upon the known methods of treatment for these respiratory diseases.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Applicants' arguments with regard to instant Claims 14-16 and 18-20 are persuasive; the rejection of these claims has thus been withdrawn. The following discussion is in response to Applicants' arguments regarding the rejection of the remaining rejected claims. Arguments with regard to Claims 1, 2, 4, 5, and 22-27 have been addressed *supra*.

As noted above, independent Claim 1 of the present application is quite broad. The claim can be reasonably interpreted to allow for administration of multiple doses of trospium to achieve "an effective therapy for at least 10 hours" of a disease which is only characterized by the presence of a constrictive airway. One of ordinary skill would have certainly recognized that the duration of action of any therapeutic agent could be extended by multiple dosing of the agent.

Applicants argue "Bernstein is directed to particle formulation and does not provide any evidence of the therapeutic effectiveness of any the hundreds of therapeutic agents listed therein (none of which are trospium). Only the physical characteristics of the particles prepared therein are tested in the Examples disclosed and then only the regional distribution of particles containing budesonide in the human lung is tested in Example 4. Bernstein provides no information or evidence with regard to the therapeutic effectiveness or hours of therapeutic effectiveness of the formulations or whether such formulations actually provide the extended release properties asserted in Bernstein." Applicants assert Richards discloses powder formulations but does not

disclose formulations of trospium. It is argued that the prior art does not disclose a fine particle fraction of at least 50%. Applicants state that fine particle fraction is defined in the Specification "as having an aerodynamic diameter of less than 3.4 microns". Applicants allege “none of the cited references discloses dry powder particles wherein the aerodynamic diameter of the actual particles in an 8 stage cascade impactor is actually measured, much less teach the fine particle fraction limitation. All of the dry particle formulations of trospium tested in the present application have an FPF of at least 50% and provided the greatest protection (greater than 20 hours) from bronchoconstriction even as compared to the aqueous composition of trospium tested (see page 15, lines 23- 30 and Figure 3). Therefore, it is unexpected that the presently claimed dry powder formulations of claim 8 and all claims dependent thereon (claims 10-13, 15 and 18-21) would have the presently claimed duration of therapy.” Applicants further argue that although Bernstein et al. teach once a day formulation administration, “how to make trospium once a day is simply not taught.”

These arguments are not persuasive. Bernstein was provided to demonstrate prior art knowledge that sustained release dry powder formulations are useful in the treatment of respiratory disease, including *inter alia* asthma and COPD. Further, the sustained release particle formulation provides local or plasma concentrations at nearly constant values over the intended period of release, allowing patients to take treatments once or twice daily. The skilled artisan would have been motivated to apply the principles taught by Bernstein to provided extended release formulations of trospium as made obvious, as discussed above, by Freund et al., Levin et al. and Richards et al.

With regard to the fine particle fraction limitation of instant Claim 8, Bernstein et al. teach the aerodynamic diameter of the formulation is adjusted to enable particle deposition by inhalation to the region of interest in the lung. Particles taught by Bernstein et al. have a volume average diameter and volume median diameter of between 1 and 5 microns, satisfying the requirements of instant Claim 8. Further, with regard to Applicants assertion of the unexpected properties of a formulation having a fine particle fraction of at least 50%, Applicants have not provided any evidence showing in support of this assertion. For example, no comparison data is provided for formulations having a fine particle fraction of less than 50%.

With regard to Applicants' argument concerning once a day dosing, it is noted that the invention of Bernstein et al. is directed to particulate sustained release pharmaceutical formulations for inhalation administration. Although Bernstein et al. do not teach trospium *per se*, they do teach anticholinergic agents in general, including ipratropium bromide, and bronchodilator/sympathimetic agents, such as formoterol.

Conclusion

13. Claims 1, 2, 4-8, 10-13, and 21-27 are rejected.

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1614

/James D Anderson/
Primary Examiner, Art Unit 1614